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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,354	07/07/99	HAVENGA M	4123US

HM22/1024

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EXAMINER	
LEE, G	
ART UNIT	**PAPER NUMBER**
1632	10

DATE MAILED: 10/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/348,354	Havenga et al.
Examiner	**Group Art Unit**
Gai (Jennifer) Mi Lee	1632

☒ Responsive to communication(s) filed on *Jul 1, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-3 and 9-11* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-3 and 9-11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply Sequence Requirements

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants amendment and declaration of Dr. Menzo Havenga under 37 C.F.R. § 1.132 filed July 1, 2000 in Paper No. 7 are acknowledged. Claims 4-8 and 12 have been canceled. Claims 1-2 and 9-10 have been amended.

Claims 1-3 and 9-11 are currently pending.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Application. Until these requirements are satisfied, the applicant remains in non-compliance with the sequence rules. Please refer to the attached notice to comply.

Information Disclosure Statement

The information disclosure statement filed August 01, 2000 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. Note that applicant needs to provide the cited reference in Form 1449 for consideration.

Claim Rejections - 35 USC § 112

The prior rejection of claims 1, 4, 5, 7-10 and 12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of applicant's amendment of the claims filed July 1, 2000.

Claim Rejections - 35 USC § 102

The prior rejection of claim 1 under 35 U.S.C. 102 (a) as bing anticipated by Gall et al, 1998 is withdrawn in view of applicant's amendment of the claim filed July 1, 2000.

The prior rejection of claims 1 and 11 under 35 U.S.C. 102 (b) as bing anticipated by Gall et al, 1996 is withdrawn in view of applicant's amendment of the claims filed July 1, 2000.

The prior rejection of claims 2-10 under 35 U.S.C. 102 (a) as bing anticipated by Stevenson et al, 1997 is withdrawn in view of applicant's amendment of the claims filed July 1, 2000.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The claims are drawn to a chimeric adenovirus comprising at least a part of a fiber protein of a first adenovirus serotype providing the chimeric virus with a desired host range and at least a part of a penton or hexon protein from a second adenovirus serotype that is less antigenic in a human than the first adenovirus serotype resulting in a chimeric adenovirus that is less antigenic in a human than the first adenovirus serotype and a method of producing such chimeric adenovirus (claims 1 and 9). In particular, where the reduced antigenicity is a diminished capability, as compared with the first adenovirus serotype to raise neutralizing antibodies and wherein the hexon, penton and/or fiber proteins are chimeric proteins originating from different adenovirus serotypes. In further embodiments, a recombinant vector derived from an adenovirus comprising at least one ITR and a packaging signal having an insertion site for a nucleic acid sequence of interest, and further having an insertion site for functionally inserting a gene encoding a penton and/or hexon protein of a first serotype of adenovirus and having an insertion site for a gene encoding a fiber protein of a second adenovirus of a different serotype, wherein the gene encoding the penton and/or hexon protein encodes a penton and/or hexon protein from an adenovirus serotype less antigenic in a human than the second adenovirus serotype and wherein the recombinant vector is a plasmid.

Claims 1-3 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Crystal et al (U.S. Patent #6,127,525).

Crystal et al teach a chimeric adenoviral coat protein (particularly a chimeric adenovirus hexon and/or fiber protein) with a decreased ability or inability to be recognized by a neutralizing antibody directed against the corresponding wild-type adenovirus coat protein (abstract) for gene therapy. Crystal et al further teach that the adenovirus coat proteins can be modified by deleting and replacing with corresponding region from another adenoviral serotype such as Ad1, Ad3, Ad5, Ad6, Ad7, Ad8, **Ad11**, Ad12, Ad14, Ad16, Ad21, Ad34, **Ad35**, Ad40, Ad41 and Ad48 of an adenovirus hexon and/or fiber or vice versa (column 7-8). Crystal et al disclose passenger gene such as therapeutic gene or a reporter gene in plasmids, intermediary plasmid vector that are employed in the construction of adenoviral vector or transfer vector (column 14-16, See also Figure 1 and 2). Crystal et al further teach a method of producing a chimeric adenovirus with a transfer vector such as an adenoviral vector (e.g., virions or virus particles) comprising a chimeric coat protein can be constructed by introducing into a cell e.g., a 293 cell, a vector comprising sequences from the adenoviral left arm, and a vector comprising sequences from the adenoviral right arm, resulting in recombination between the sequences, generating a vector that comprises a portion of each of the vectors (column 18). Thus, Crystal et al clearly anticipate claims 1-3 and 9-11 of the instant invention.

Applicants submitted a declaration under 37 C.F.R.§ 1.132 of Dr. Havenga's work demonstrating the range of antigenicities for the various human adenovirus serotypes tested does not overcome the rejection under 35 U.S.C. 102 (e) as being anticipated by Crystal et al, above. Dr. Havenga discloses materials, methods, procedures, and results demonstrating the range of

antigenicities by testing for the presence of neutralizing antibodies against a panel of 44 human adenovirus serotypes. Dr. Havenga discloses that not only is the frequency of NA to Ad35, Ad11 and Ad49 much lower as compared to Ad5, but of the sera that do contain NA to these viruses, the vast majority has low titers. Thus, Dr. Havenga further supports Crystal et al in producing a chimeric adenovirus that is clear advantage over Ad5 based vectors when used as gene therapy vehicles or vaccination vectors in vivo or in any application where infection efficiency is hampered by neutralizing activity.

Claim Rejections - 35 USC § 103

The prior rejection of claims 1-11 under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al, 1997 in view of Gall et al, 1996 are withdrawn in view of applicant's amendment to the claims filed July 1, 2000.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gai (Jennifer) Mi Lee, whose telephone number is 703-306-5881. The examiner can normally be reached on Monday-Thursday from 8:30 to 5:00 (EST). The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on 703-305-6608. The FAX phone numbers for group 1600 are 703-308-4242 and 703-305-3014.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is 703-308-0196.

Gai (Jennifer) Lee
Patent Examiner
Art Unit 1600

Karen M. Hauda
KAREN M. HAUDA
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